DELAWARE HEALTH AND SOCIAL SERVICES

RESEARCH ABSTRACT

FOR APPLICATION TO
THE HUMAN SUBJECTS REVIEW BOARD (HSRB)
(Revised December 2005)

The form below is to be completed for all projects involving research and human subjects within the Department of Health and Social Services, in compliance with DHSS Policy Memo 55 and Policy Memo 60.

In addition to completion of the form provided here, the researcher will need to submit any proposal prepared for the funding agency to the HSRB.

The researcher also needs to sign and submit an Investigator's Agreement, which is available from the HSRB chairperson, and a Certificate of Completion of Training on Human Subjects Protection.

Item 19 below relates to review of the project by the Attorney General's Office. This submission is to be handled by the Division Director and should be done prior to submitting the material to the Human Subjects

Review Board so that any comments from that Office can be used by the Board in its deliberations. The need for this is to be handled on a case-by-case basis.

Once the form below is completed and signed by the Researcher and the Division Director, one hard copy original of all signed materials, including the Investigator's Agreement, and the Training Certificate, should be sent to: Linda Barnett, Division of Management Services, DHSS, Main Building, Herman Holloway Sr. Campus, 1901 N. DuPont Highway, New Castle, DE 19720. In addition, all project materials should be sent electronically to Ms Barnett (linda.d.barnett@state.de.us).

If there are any documents not available electronically and for those project documents which are extremely lengthy, then fifteen ***paper*** *copies will need to be supplied. For clarification of these instructions, Ms Barnett can be reached at 302-255-9133.*

Project Descriptions; check all that apply:
☐ Must be HIPAA-compliant; involves protected health information maintained by a 'covered entity'
☐ Meets the criteria for exemption from HIPAA compliance allowed under 45 CFR Sec 164.512 (b)(i): involves protected health information to be used by a public health authority for a public health purpose
☐ Access to protected health information included in this project will require tracking on the part of _____ in order to be able to comply with the HIPAA provision that individuals, upon request, must be given an accounting of certain disclosures of their protected health information
☐ No protected health information is involved; does not require HIPAA compliance

1.Title of project

2.Name, address, agency, e-mail address, and phone number of principal investigator(s) or project manager(s)

3.Division whose clients/consumers will serve as research subjects

4.Name and phone number of Division contact person for the project

5.Role of Divisional staff in the project

6.Purpose of project; hypotheses; or research questions (including information to substantiate the scientific merit of the project)

7.Subjects or Population to be Studied

a. Age, gender(s) and approximate number

b. Inclusion/exclusion criteria

8.Method(s) of Recruitment, including plan for determining and recording reasons for refusal to participate

9.Compensation/Inducements to Participate:

10.Method for obtaining prior informed consent and HIPAA authorization – if applicable [include copy of form(s) to be used]. Describe plan(s) for maximizing participant understanding of the forms, including determination of reading level.

11.Method for dealing with research subjects who choose to withdraw from the project and/or revoke their authorization, to include procedures for ensuring that participants understand these are or can be two separate steps.

12.Description of any protected health information that is being requested from DHSS files (or the files of its contractor agencies) for this research project, along with the justification for needing such information (in order to comply with the "minimum necessary" rule in the HIPAA regulations)

13.Methodology and/or description of project approach, including description of plans for data collection and methods that will be used to analyze data, if applicable (include copies of proposed data collection instruments)

14.Methods for ensuring privacy and confidentiality of data collected [include copy(ies) of the Notice of Privacy Practices for the Covered Entity(ies) which maintain(s) the protected health information to be accessed, if applicable] .

15.Costs/Funding

a. Cost of project to DHSS

b. Funding source(s)

c. Source of funding after research or pilot phase, if applicable

16.Timeframe

a. Target start date

b. Completion date

17.Are subjects/clients at risk? If yes, delineate steps to be taken to minimize risks

18.Anticipated benefit to subjects or society

19.Review by Attorney General's Office, if applicable

a. Date sent for review

b. Feedback received

Submitted by: _____
Signature of Researcher/Title/Date
My signature attests to my agreement to carry out this project in accordance with the principles of the Common Rule and the Privacy Rule.

Approved by: _____
Division Director/Date
My signature attests to my understanding of and agreement to any HIPAA-related obligations imposed by this project, including any necessary recordkeeping to be able to account for disclosures as mandated by HIPAA regulations.

Approved by: _____
Chairperson, DHSS HSRB/Date
My signature attests to the fact that this project was reviewed and approved by the DHSS Human Subjects Review Board / Privacy Board.

Approved by: _____
Secretary/Date